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December 4, 2019

VIA ECF

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, NJ 08101

Re: In re Valsartan NDMA Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

Please accept the within on behalf of the Core Discovery Defendants.[1]

The Court has called for "letter briefs on the issue of whether the Court should strike *defendants'* redactions of the FDA documents produced to plaintiffs." Doc. 303, at 1 (emphasis supplied). The redaction issue first came up in the Court's email of November 18, 2019, to the undersigned and Mr. Slater with reference to footnotes 4 and 18 from Plaintiffs' macro discovery response brief. Those footnotes, however, discussed "FDA documents obtained by Plaintiffs pursuant to FOIA requests, and/or that are publicly available on the internet" and, therefore, they were "heavily redacted pursuant to the *FDA's* public release of information." Doc. 296, at 6 n.4 (emphasis supplied). In contrast, the redactions made by counsel in the core discovery productions pursuant to the ESI Protocol related to two categories of information: (A) HIPAA material and (B) references to and documents concerning non-valsartan products. These redactions are separate and

[1] The "Core Discovery Defendants" being the API and finished dose manufacturers in the litigation and the FDA liaisons for those foreign manufacturing defendants which had not been served at the time of core discovery.

apart from the redactions made by FDA in producing documents to Plaintiffs in response to FOIA requests.

Plaintiffs have since identified twenty bates-numbered documents that they have requested be produced for *in camera* review by Your Honor. Copies of those documents are being provided to Your Honor via hard copy for *in camera* review. The Core Discovery Defendants are not making their own additional designations as they believe the documents selected by Plaintiffs reflect the various bases for the redactions to core discovery.

Plaintiffs' request for Court intervention to obtain production of unredacted core discovery documents produced pursuant to the ESI Protocol is procedurally premature in that Plaintiffs have never written or otherwise communicated to Defendants objecting to the redaction of either HIPAA information or information concerning other drugs. Likewise, Plaintiffs never met–and-conferred with Defendants about the bases for the redactions.

Furthermore, the parties have only just received the benefit of the Court's November 25, 2019 Order ruling on a number of macro discovery issues. Doc. 303. The Core Discovery Defendants are in the process of reviewing redacted core discovery documents to ascertain if any of those documents now need to be produced in unredacted form in light of Your Honor's ruling. Again, that may alleviate some of Plaintiffs' objections to the redactions without necessitating Your Honor conduct an *in camera* review.

Nonetheless, given Your Honor's directive that the December 11th conference is a hard deadline to resolve outstanding discovery issues, the Core Discovery Defendants maintain that there is no basis for a blanket order requiring production of unredacted core discovery documents.

A. <u>Redactions by FDA in response to Plaintiffs' FOIA requests.</u>

As part of the briefing on macro discovery issues, Plaintiffs claimed that they are "entitled to the full, unredacted versions of [documents reflecting inspections of finished-dose facilities], which are in the Defendants' custody and control but have not been produced to Plaintiffs." Doc. 296, at 6 n.4. The redactions of a "multitude of pages" referenced by Plaintiffs, *id.* at 19 n.18, were made *by FDA* in order to prevent the public disclosure of the Core Discovery Defendants' proprietary process information and trade secrets.

Notably, Plaintiffs insisted that the core discovery productions be made in accordance with the ESI Protocol, *see e.g.*, Doc. 116, at 3. The ESI Protocol—a product of many months of negotiations—entered in this MDL expressly permits redaction of "information contained in a document . . . that is non-responsive because it does not concern the product(s) at issue nor is relevant to any party's claims or defenses[.]" Doc. 127, at 18–19. Accordingly, Defendants' production of documents regarding FDA inspections of API facilities contained limited, discrete redactions which, in most instances, were limited to the name of the other product being discussed.

All core discovery disputes were to be raised and resolved at the August 14, 2019 in-person conference. Doc. 167, CMO-10 ¶ 1. Plaintiffs did not raise any issues with Defendants' redactions, *see* Doc. 178, and the litigation shifted from core discovery to Rule 34 and ESI discovery. On November 20, the Court resolved the parties' "macro" dispute with respect to the scope of discovery concerning finished-dose products and facilities and, of course, Defendants will be producing materials in compliance with the Court's oral opinion delivered from the bench and the resultant written Order. *See* Doc. 303.

In other words, documents concerning inspections of finished-dose facilities—the very documents Plaintiffs demanded in their macro discovery brief—will be produced, albeit with limited, discrete redactions of information pertaining to drugs other than valsartan in the same manner as Defendants' core discovery productions, to the extent not done already.[2] Accordingly, Defendants respectfully submit that the process should be allowed to run its course and if, upon receipt of Defendants' finished-dose inspection production, Plaintiffs believe that the redactions Defendants will have made are inconsistent with the ESI Protocol, then the parties can engage in a meet and confer to see if some resolution can be reached.

B. Redaction of HIPAA information by Core Discovery Defendants.

As outlined above, the concern raised by Plaintiffs in their macro discovery brief related to redactions made *by the FDA* with respect to finished-dose inspection documents *produced by the agency* in response to FOIA requests. Yet, the issue has somehow morphed into a retrospective analysis of whether the Court should enter a sweeping order striking all redactions made by Defendants in their core discovery productions—despite the fact that Plaintiffs never challenged the propriety of those redactions. Be that as it may, the first category of redactions by the Core Discovery Defendants in their core discovery productions relates to HIPAA protected information. For example, Defendants have redacted patient information contained within the bioequivalence studies produced as part of the ANDA files. The Core Discovery Defendants fail to see how production of unredacted personally identifiable information and other HIPAA materials is relevant to any party's claims or defenses, and based on the fact that none of the 20 documents identified by Plaintiffs for review by the Court contain HIPAA redactions, Defendants assume that Plaintiffs are not making such a demand.

C. Redaction of information related to other products by Core Discovery Defendants.

The second category of redactions by the Core Discovery Defendants concerns products other than valsartan that, likewise, are irrelevant to any party's claims or defenses currently at issue in this MDL and are consistent with the Court's prior directives on this topic. Your Honor's

[2] Aurolife Pharma LLC produced inspection reports in core discovery that included redactions of references to non-valsartan products. All redactions were made pursuant to the ESI Protocol (CMO-8, Doc. 127).

November 25, 2019 Order already denied "Plaintiffs' request for discovery regarding other products using the same manufacturing processes, solvents, and testing as those for Valsartan API" subject to Defendants producing documents reflecting the presence of any nitrosamine in valsartan, losartan, irbesartan, olmesartan, and candesartan. Doc. 303, ¶ 4. Your Honor's ruling on this issue was specific to the production of "documents reflecting the presence of any nitrosamine in any sartan product made *prior to July 2018*." *See* Oral Opinion Deciding the Parties' "Macro" Issues Listed in the October 22, 2019 Order, Doc. 280, T17:10-12; *see also id.* at T16:1-17:14 (noting only valsartan is currently at issue in this case, the burden and expense of producing such discovery "is disproportional to its importance and relevance", and discovery into other sartans "will divert the parties' resources and attention away from the core issues in dispute").

These rulings are consistent with the ESI Protocol[3] entered in this litigation that provided a producing party may redact information in a document or withhold an entire document "that is non-responsive because it does not concern the product(s) at issue nor is relevant to any party's claims or defenses" subject to the producing party segregating the non-responsive information from any responsive information to not impede a receiving party's ability to interpret the responsive information contained in the document. Doc. 127 at pp. 18–19. Such documents were to be produced and clearly marked "Redacted – Other Product(s)" or "Withheld – Other Product(s)" as warranted.

Of the hundreds of thousands of pages produced as part of core discovery, a small percentage contained "other product" redactions or were withheld as relating to other products. In many instances, the redactions were limited to the chemical name of the API or drug being discussed. The facilities at issue have manufactured dozens or even hundreds of products since 2010. As such, it is commonplace in FDA correspondence to have discussions regarding any number of products not at issue in this litigation. For example, an Establishment Inspection Report might read, "This inspection focused on [REDACTED – OTHER PRODUCT] manufacturing for cGMP evaluations for the manufacturer's packaging systems." *See, e.g.*, PRINSTON00077533 (483 response redacting information for non-valsartan drugs); PRINSTON00073421 (Form 483 redacting information for non-valsartan drugs); PRINSTON00071746 (Establishment Inspection Report redacting information for non-valsartan drugs)[4]; AURO-MDL-2875-0077720

[3] Moving forward, the Core Discovery Defendants will continue to produce documents in accordance with the Court's orders and instructions, including the ESI Protocol. And, as always, Defendants stand ready and willing to engage in a meet and confer in the event Plaintiffs raise specific concerns with respect to particular redactions in the Core Discovery Defendants' productions.

[4] PRINSTON00071746, is a document sent to ZHP by the FDA. The document provided to ZHP by the FDA contained redactions made by the FDA. ZHP's production of this document included the FDA's redactions and additional redactions made by ZHP's counsel for the purpose of producing the document in this action. ZHP is supplying a copy of this document to the Court with all redactions applied by counsel removed, but is unable to remove the redactions applied by the FDA.

(Establishment Inspection Report redacting information for non-valsartan drugs); AURO-MDL-2875-0077785 (Establishment Inspection Report redacting information for non-valsartan drugs); AURO-MDL-2875-0077806 (Establishment Inspection Report redacting information for non-valsartan drugs); AURO-MDL-2875-0077812 (Establishment Inspection Report redacting information for non-valsartan drugs); MYLAN-MDL2875-00030165 (Establishment Inspection Report reflecting a "product specific inspection" concerning non-valsartan API) MYLAN-MDL2875-00030258 (Establishment Inspection Report concerning an inspection "focused on" non-valsartan API); MYLAN-MDL2875-00030326 (Establishment Inspection Report "focused on" the manufacture and testing of non-valsartan API).

Redactions were also made in communications with FDA about sources of the impurities and responsive measures taken since the valsartan recall was announced. Some of those communications discussed not only valsartan but other products. Redactions were made to these written responses to FDA concerning specific action items taken in regard to other products since the valsartan recall was announced while leaving discussion of the valsartan related inquiries and responses intact including investigation of complaints, findings of nitrosamine impurities, and corrective actions. *See, e.g.*, HETERO_USA000028942 (Written submission for meeting with FDA redacting information for non-valsartan drugs), HETERO_USA000028977 (Email to FDA appending various attachments concerning valsartan and other products redacting information for non-valsartan drugs), HETERO_USA000029502 (Response to action items from meeting with FDA redacting information for non-valsartan drugs), HETERO_USA000028954 (Response and status report to FDA redacting information for non-valsartan drugs). Similarly, the other product documents withheld by the Core Discovery Defendants include testing results and product specification details for non-valsartan products provided to FDA since the July 2018 valsartan recall was announced. *See, e.g.*, HETERO_USA000029128 (Results from testing of non-valsartan drugs conducted after valsartan recall announced). These documents were specifically marked in conformity with the ESI Protocol as "Withheld-Other Products". *Id.*

The parties have now argued, and the Court has largely resolved, issues relating to the scope of discovery with respect to finished-dose manufacturing facilities and, of course, the Core Discovery Defendants will adhere to that ruling. *See* Doc. 303. At the same time, the Court's Order makes clear that, outside of narrow circumstances—i.e., "documents reflecting the presence of any nitrosamine in any sartan product," *id.* at 3—discovery in the *In re Valsartan* MDL is limited to information pertaining to valsartan. Defendants' redactions of the names of other products and withholding of testing for other products either unrelated to nitrosamine contamination or conducted and submitted to FDA *following after* July 2018 are consistent with the Court's directives in this case. *See* Oral Opinion Deciding the Parties' "Macro" Issues Listed in the October 22, 2019 Order, Doc. 280, at T16:1-17:14. The redactions do not interfere with Plaintiffs' ability to understand the substance of FDA's observations or the comments being made by the responding party with regard to the relevant products nor do they interfere with discovery of the central issues in this case concerning where and how the nitrosamine impurities arose and what, if any, potential risks are posed by the impurities.

The Court, in its various discovery rulings, has struck a balance between the overarching need to focus discovery on the product actually at issue, valsartan, and Plaintiffs' request for additional information. Their demand for an *ex post facto* order striking all redactions flaunts that balance—and for no apparent reason other than a desire to peruse Defendants' highly sensitive information. But "[f]ishing expeditions during which a party searches for evidence to support claims or defenses not yet pleaded are not permitted." *Dix v. Total Petrolchemicals USA, Inc.*, No. 1:10-cv-3196, 2011 WL 5513185, at *3 (D.N.J. Nov. 10, 2011) (internal citations omitted). Indeed, "[t]he discovery rules are designed to assist a party to prove a claim it reasonable believes to be viable without discovery, not to find out if it has any basis for a claim." *Claude P. Bamberger Int'l, Inc. v. Rohm & Haas Co.*, No. 2:96-cv-1041, 1998 WL 684263, at *2 (D.N.J. Apr. 1, 1998) (quoting *Micro Motion, Inc. v. Kane Steel Co., Inc.*, 894 F.2d 1318, 1326 (Fed. Cir. 1990)).

Thus, the Core Discovery Defendants respectfully submit that their redactions were appropriate and that they should not be required to bear the burden of producing unredacted copies of the previously produced core discovery documents. The information sought is of minimal relevance at best, irrelevant in large part, and the time and expense of making supplemental productions is disproportional to the interests of the parties in asserting their claims and defenses.

Accordingly, for the foregoing reasons, the Core Discovery Defendants respectfully request Plaintiffs' request that the core discovery be reproduced without redactions be denied.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

SAG
Enclosures

cc: Adam Slater, Esq. (*via email*, *for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email*, *for distribution to Defendants' Counsel*)
Lori G. Cohen, Esq. (*via email*)
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